

II. REMARKS

Formal Matters

Claims 32-36 and 38-44 are pending after entry of the amendments set forth herein.

Claims 32-36 and 38-43 were examined and were rejected.

Claims 32 and 40 are amended. The amendments to the claims were made solely in the interest of expediting prosecution, and are not to be construed as acquiescence to any objection or rejection of any claim. Support for the amendment to claim 32 is found in the claims as originally filed, and throughout the specification, in particular at the following exemplary locations: page 18, line 9 to page 19 line 2. No new matter is added by the amendments to claims 32 and 40.

Claim 44 is added. Support for new claim 44 is found in the claims as originally filed, and throughout the specification, including the following exemplary locations: page 18, line 9 to page 19 line 2. Accordingly, no new matter is added by these new claims.

Applicants respectfully request reconsideration of the application in view of the remarks made herein.

Rejection under 35 U.S.C. §102(b)

Claim 40 was rejected under 35 U.S.C. §102(b) as allegedly anticipated by Draper et al. (U.S. Patent No. 5,514,577; "Draper").

The Office Action stated that Draper teaches SEQ ID NOs:47, 48, and 51, where these sequences comprise GGIGTT, GGGITT, and GGGGTT, respectively. The Office Action stated that each of the sequences set forth in SEQ ID NOs:47, 48, and 51 is less than 45 nucleotides in length. Applicants respectfully traverse the rejection.

The sequences GGIGTT and GGGITT are not recited in claim 40. As such, SEQ ID NO:47 and SEQ ID NO:48 of Draper, which include the sequences GGIGTT and GGGITT, respectively, do not appear to be relevant to claim 40.

Claim 40 as amended does not recite GGGGTT, which is included in SEQ ID NO:51 of Draper. As such, Draper does not anticipate claim 40 as amended.

Applicants submit that the rejection of claim 40 under 35 U.S.C. §102(b) has been adequately addressed in view of the remarks set forth above. The Examiner is thus respectfully requested to withdraw the rejection.

Rejections under 35 U.S.C. §103(a)

Claims 32, 33, 35, and 36 were rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Bennett et al. (WO 91/16901; "Bennett") in view of Barsoum et al. (WO 94/04686; "Barsoum"). Claims 40 and 41 were rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Draper in view of Barsoum. Claims 42 and 43 were rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Draper and Barsoum in view of Bennett.

Claims 32, 33, 35, and 36 over Bennett in view of Barsoum

The Office Action stated:

- 1) Bennett teaches a nucleic acid of SEQ ID NO:12 (GGAAAGGTTCCAGGGAAGAGG), where the nucleic acid is in a pharmaceutically acceptable carrier;
- 2) Bennett teaches analogs encompassing phosphorothioate moieties;
- 3) Bennett differs by not conjugating to a peptide;
- 4) Barsoum teaches delivery of cargo molecules, such as nucleic acids, to the cytoplasm and nuclei by use of a transport polypeptide that comprises one or more portions of HIV tat protein which are covalently linked to cargo molecules.

The Office Action stated that it would have been obvious to conjugate the nucleic acid of Bennett to the transport peptides of Barsoum. Applicants respectfully traverse the rejection.

Bennett discusses antisense oligonucleotides. Bennett describes introducing antisense oligonucleotides into cells in medium alone or in medium containing DOTMA. Bennett, pages 30, 34, and 35; and Examples 1, 5, and 6. Bennett states that various antisense oligonucleotides reduced levels of 5-lipoxygenase significantly. Bennett, page 33, lines 32-35. There is no discussion in Bennett of difficulty in getting the antisense oligonucleotides into cells.

Barsoum discusses use of a Tat polypeptide for cytoplasmic and nuclear delivery of biologically active non-tat proteins, nucleic acids and other molecules that are not inherently capable of entering target cells or cell nuclei, or are not inherently capable of entering target cells at a useful rate. Barsoum, page 5, lines 13-20. Bennett does not characterize the antisense oligonucleotides discussed therein as “not inherently capable of entering target cells or cell nuclei,” or “not inherently capable of entering target cells at a useful rate.” As such, there would be no motivation in the cited references to combine the reference teachings. Accordingly, Bennett, alone or in combination with Barsoum, cannot render any of instant claims 32, 33, 35, and 36 obvious.

Nevertheless, and solely in the interest of expediting prosecution, claim 32 is amended to recite “wherein the nucleic acid is conjugated to an autoantigen or an autoantibody.” Barsoum neither discloses nor suggests a nucleic acid conjugated to an autoantigen or an autoantibody. Accordingly, Bennett, alone or in combination with Barsoum, cannot render any of instant claims 32, 33, 35, and 36 obvious.

Claims 40 and 41 over Draper in view of Barsoum

The Office Action stated that Draper teaches SEQ ID NOS:47, 48, and 51, where these sequences comprise GGIGTT, GGGITT, and GGGGTT, respectively. The Office Action stated that each of the sequences set forth in SEQ ID NOS:47, 48, and 51 is less than 45 nucleotides in length. The Office Action stated that Draper differs by not conjugating to a peptide. The Office Action stated that it would have been obvious to conjugate nucleic acids of Draper to the transport peptide of Barsoum. Applicants respectfully traverse the rejection.

As noted above, the sequences GGIGTT and GGGITT are not recited in claim 40. As such, SEQ ID NO:47 and SEQ ID NO:48 of Draper, which include the sequences GGIGTT and GGGITT, respectively, do not appear to be relevant to claim 40.

Claim 40 as amended does not recite GGGGTT, which is included in SEQ ID NO:51 of Draper. As such, Draper, alone or in combination with Barsoum, cannot render claim 40 or 41 obvious.

Claims 42 and 43 over Draper and Barsoum in view of Bennett

The Office Action stated that the combination of Draper and Barsoum is that set forth in the rejection of claims 40 and 41. The Office Action stated that Bennett teaches that oligonucleotide analogs such as phosphorothioate function to enhance the ability of the compositions to penetrate into regions of the cells where the RNA and DNA whose activity is to be modulated. The Office Action stated that it would have been obvious to modify the nucleic acid in the composition to substitute native linkages with analog linkages as taught by Bennett. Applicants respectfully traverse the rejection.

As noted above, the sequences GGIGTT and GGGITT are not recited in claim 40. As such, SEQ ID NO:47 and SEQ ID NO:48 of Draper, which include the sequences GGIGTT and GGGITT, respectively, do not appear to be relevant to claims 42 and 43.

Claim 40, from which claims 42 and 43 depend, is amended such that it does not recite GGGGTT, which is included in SEQ ID NO:51 of Draper. As such, Draper, alone or in combination with Barsoum or Bennett, cannot render claim 42 or 43 obvious.

Conclusion as to the rejections under 35 U.S.C. §103(a)

Applicants submit that the rejections discussed above under 35 U.S.C. §103(a) have been adequately addressed in view of the remarks set forth above. The Examiner is thus respectfully requested to withdraw the rejections.

III. CONCLUSION

Applicants submit that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number UCSD-173 CON.

Respectfully submitted,
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